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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,803

08/17/2006

Tsunenori Arai

081356-0266

2407

22428 7590 03/09/2011

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EXAMINER

LIPITZ, JEFFREY BRIAN

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

03/09/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,803	Applicant(s) ARAI ET AL.	
	Examiner JEFFREY B. LIPITZ	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/14/2010 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/14/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed February 1, 2011 with respect to the drawing objections have been fully considered but they are not persuasive. Examiner acknowledges the petition filed; however, the objection must be maintained until the granting of that petition per the requirements of the MPEP.

Applicant's arguments with respect to the written description rejections of claims 21, 24 and 25 have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, the sheath and the optical fiber can only be pulled out during welding when the sheath and fiber are fastened to one another, as disclosed on Page 18 of the original disclosure. Therefore, this step requires the limitations of claim 25 to be included in the independent claim. A 112 rejection has been made.

Applicant's arguments with respect to the enablement rejection of claim 25 have been fully considered but they are not persuasive. Applicant asserts that an informed skilled person would know how to immovably fasten the sheath to the fiber. Examiner disagrees. Applicant has NOT provided adequate detail regarding the fastening of one element to the other. The step of fastening is further complicated because it must be performed during the procedure. The sheath and the fiber cannot merely be formed as a single unit. It remains unclear how a skilled artisan would perform this step during the procedure, and it is further unclear why Applicant believes the step to be known to those of ordinary skill in the art. Applicant's claimed method hinges on the fastening of these

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two elements in order to remove the sheath and fiber during the step of welding.

Therefore, it seems odd that Applicant would take the position that this critical step is a step readily known to other skilled artisans. This method is contingent on a very specific system, and would not be applicable to any system used to close vessel holes. This rejection has been maintained.

Applicant's arguments/amendments with respect to the prior art rejections have been fully considered and are persuasive. Applicant has amended the claims to limit the identification of tissue to be contingent on the detected intensity of the back-scattered or reflected light. Balbierz (20020026188) teaches using optical intensity measurements to differentiate between tissues. This reference has been added accordingly.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the balloon or stent, the propelling means and or micrometer screw, and the temperature measuring means or thermocouple must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

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is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In this claim, Applicant recites fastening the optical fiber and the sheath together. However, it is unclear from the disclosure how this step would be performed. How do the elements attached to one another? What elements enable them to be fastened together? See the response to arguments supra for further details.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-24 and 26-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the fastening of the sheath to the fiber(s), as discussed further in the response to arguments *supra*.

Regarding claim 24, Applicant recites "monitoring...to ascertain when there is a rise in intensity of backscattered light that is absorbed into the tissue, where such a rise is indicative that the tissue that surrounds the distal end of the element is a blood vessel." This statement is confusing and misleading. The blood vessel is identified when *more* light is absorbed, since the wavelengths used are absorbed by substances present in blood; and thus less backscattered light is detected. In its current form, the limitation is unclear because it is not clear if a rise of intensity is indicative of a blood vessel at the distal tip of the device (See Applicant's Figure 4B).

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claim 31 is rejected under 35 U.S.C. 112, fourth paragraph, as being claims in dependent form that do NOT specify a limitation that further limits the subject matter of

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the claim from which it depends. Applicant discloses that the fiber is moved to determine the end position of the fiber during welding, which *must* occur at the same time as the step of monitoring (Applicant's disclosure Page 16). Examiner has interpreted claim 31 accordingly; and therefore, the rejection directed to the limitation in claim 24 concerning movement of the fiber is also applicable here. This claim does NOT further limit the scope of the claim because the step of moving the fiber must be done manually or by a device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-26 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinofsky (5725522) in view of Hennings et al. (20050131400), hereinafter Hennings, and further in view of Balbierz et al. (20020026188), hereinafter Balbierz.

Regarding claims 22, 24 and 26, Sinofsky teaches methods that repair blood vessel incisions comprising: introducing a sheath or tube or casing (70 or 81; Figures 3, 7 and 8) that includes at least one optical fiber (72 and 74; Col. 8, Lines 1-12). Illumination fibers (74) carry illumination light to the [potential] treatment area and carry reflected light back to a reflectance monitor (18; Figure 1). The monitor (18) is coupled to a display (24), which provides a visual display of the region during the procedure

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(Columns 5-6). Sinofsky also teaches providing welding laser light via laser port (83; Figure 3) or central fiber (72; Figures 7-8), and directing the light to a cross-linking agent or glue or pigment (Col. 2, Lines 53-60; Col. 4, Lines 25-67). Sinofsky is silent as to when the pigment is applied. However, it would have been necessary to provide the pigment before or during the step of welding because the purpose of providing the pigment is to enhance the welding process and the pigment is photosensitive. It would have been obvious to provide the pigment during the step of welding because doing so would ensure that there was sufficient pigment to facilitate welding tissue.

Sinofsky does NOT explicitly teach that the monitoring step is used to determine that the tissue is a blood vessel. However, since the monitor provides a visual display to the user, it would have been obvious to a skilled artisan to check that display prior to welding the tissue.

Sinofsky does NOT teach that the sheath/optical fiber are pulled away from the hole during irradiation. Attention is directed to Hennings who teaches venous closure methods/apparatuses that including providing a laser (102) delivered via a fiber optic catheter (300) and a pull-back device (104) for motorized withdrawal of the fiber optic during irradiation of the vessel wall (Abstract and Paragraph [0134]). Hennings also admits that the concept of withdrawing an emitting fiber optic was known in the prior art (Paragraph [0013]). It would have been obvious to pull the sheath/fiber away from the hole during irradiation, because doing so would help to prevent overheating of the adjacent tissue/vessel.

Sinofsky and Hennings do NOT teach using the light intensity in particular to detect blood vessels. Attention is directed to Balbierz who teaches detecting scattered/reflected light from tissue to identify and differentiate between tissues (Paragraph [0066]; Figures 5, 7). Balbierz teaches analyzing spectral profiles, which include light intensity, to differentiate between tissues (Paragraphs [0057], [0067], [0072] and [0076]). It would have been obvious to monitor intensity of backscattered light in particular because it requires a less complicated set-up, it does not require imaging and it can be performed simultaneously with welding.

Regarding claim 23, Sinofsky illustrates that the distal ends of the fibers are located at the same position along the length of the sheath (Figures 3, 7 and 8).

Regarding claim 25, Sinofsky inherently discloses that the fibers and the sheath are fastened to one another, since the fibers are housed within the tubes (70 or 81) and are clearly moved with the sheath at all times.

Regarding claims 29 and 30, Sinofsky does NOT teach measuring temperature at the distal end of the fibers with a thermocouple. Attention is again directed to Hennings who teaches installing a thermocouple on the distal end of the fibers (Paragraph [0081]). It would have been obvious to modify the device of Sinofsky to include thermocouples because doing so would enable monitoring of the vessel wall temperatures, which are indicative of damage via excessive heat or a lack of welding due to insufficient heat. Therefore, the thermocouples would enable a skilled artisan to determine the effectiveness of the treatment and monitor unintended tissue damage.

Regarding claim 31, Applicant discloses that the fiber is moved to determine the end position of the fiber during welding, which *must* occur at the same time as the step of monitoring (Applicant's disclosure Page 16). Examiner has interpreted claim 31 accordingly; and therefore, the rejection directed to the limitation in claim 24 concerning movement of the fiber is also applicable here. This claim does NOT further limit the scope of the claim because the step of moving the fiber must be done manually or by a device.

Regarding claim 32, Sinofsky and Hennings do NOT teach using a micrometer screw in particular. However, Hennings does teach using a pull-back device (104) for motorized advancement/retraction of the fibers, as discussed in the rejection of claim 24, *supra*. Examiner interprets this device as a functional equivalent of a micrometer screw, since both can translate fibers with micrometer accuracy. It would have been obvious to substitute a micrometer screw for the propelling device of Hennings because the screw is cheaper and commercially available.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sinofsky and Hennings as applied to claim 24 above, and further in view of Kittrell et al. (4913142), hereinafter Kittrell.

Regarding claim 21, Sinofsky and Hennings do NOT teach using one fiber for providing monitoring and treatment light. Attention is directed to Kittrell who teaches laser cauterization methods and apparatuses (Background and Summary of the Invention). The apparatus comprising: a laser or generator such as an argon laser, or a NG:YAG laser (Column 3, Lines 41; Column 7, Lines 40-56; Lines Column 24, Lines 60-

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69), a single optical fiber (20; Column 22, Lines 31-48; Figure 27), a beam splitter (50 or 52; Figures 21 and 22), and a detector (70 and 64), such as an array of photodiodes, configured to measure the intensity of backscattered light, and a computer (80) for determining the position of an end of the welding laser transmitting means or the distance to the tissue (Column 20, Lines 37-49). Kittrell teaches supplying diagnostic or monitoring light through a selected optical fiber (20a-c), where the light falls on the tissue and is absorbed and scattered. The light then re-enters the distal ends of the various fibers (20) where it travels to the proximal end to be analyzed by a detector (64). The light may be transmitted through the same optical fiber or a different one (Column 24, Lines 17-38). It would have been obvious to use the Figure 27 apparatus of Kittrell to perform the method of Sinofsky and Hennings because it is capable of performing all of the functions of Sinofsky, but with fewer elements.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinofsky and Hennings as applied to claim 24 above, and further in view of Sinofsky (4929246), hereinafter Sinofsky246.

Regarding claims 27 and 28, Sinofsky and Hennings do NOT teach applying pressure to the vessel during the step of welding. Attention is directed to Sinofsky246 who teaches a method for closing and sealing an artery (Abstract). Sinofsky teaches providing a balloon to apply pressure to the hole during welding (Abstract and Col. 3, Lines 47-61). Sinofsky246 does NOT teach applying the pressure from the inside of the vessel. However, it would have been obvious to provide pressure from either side of the vessel because doing so would aid in the blockage of blood flowing out of the

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vessel. It would have been particularly advantageous to apply pressure from within the vessel because doing so would have enabled the vessel to be structurally supported in the manner it normally functions.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY B. LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Thursday, 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on (571)272-4768. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEFFREY B LIPITZ/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art
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